510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K120631 MAY 25 2012

Submitter

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Registration # 1066270

Official correspondent :

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Date Prepared:

February 29, 2012

Device name and classification:

- **Device Name:** Patient Monitor models PM-2000XL & PM-2000XL Pro
- **Classification Name:** Patient Physiological Monitor (with arrhythmia detection or alarms)
- **Product code:** MHX, DRT, DXN, DSK, FLL, DQA, CCK, CBQ, CBS, CBR, CCL, DSA, DRT, DSF, and MLD
- **Regulatory Class:** Class II

Predicate Device:

M50 & M80 Patient Monitor K110922 Manufacturer: EDAN Instruments

Device Description:

The **PM-2000XL & PM-2000XL Pro** Patient Monitors provide the following primary features:

PM-2000XL & PM-2000XL Pro Patient Monitor can perform long-time continuous monitoring of multiple physiological parameters. Also, they are capable of storing, displaying, analyzing and controlling measurements, and they will indicate alarms in case of abnormity so that doctors and nurses can deal with them in time.

PM-2000XL Patient Monitor can monitor parameters including SpO_2, NIBP, EGG RESP, TEMP, C02, IBP

PM-2000XL Pro Patient Monitor can monitor parameters including SpO2, NIBP, ECG RESP, TEMP, C02, IBP, C.O. and AG

PM-2000XL is outfitted with a 8.4-inch display screen, **PM-2000XL Pro** is 15-inch, as well as an equal large touch screen, which enables the operation by touching the screen, thus offering convenience for doctors and nurses.

PM-2000XL Patient Monitor has parameter modules including SpO_2 (pulse oxygen saturation, pulse rate and SpO2 plethysmogram) with EDAN SpO2 module or Nellcor SPO2 module, NIBP (systolic pressure, diastolic pressure, mean pressure and pulse rate), TEMP, EGG RESP, C02, IBP and Quick Temp.

PM-2000XL Pro Patient Monitor has parameter modules including SpO2 with EDAN-Sp02 module or Nellcor SPO2 module, NIBP with EDAN NIBP module or Omron M3600, TEMP, EGG, RESP, C02, CO, IBP, AG.

The EDAN SpO2 module used in PM-2000XL Pro and PM-2000XL is also used by HI 100B Pulse Oximeter which has been cleared by FDA under K110922. The C02 module and Nellcor SpO2 module used in PM-2000XL Pro are the same to those used in M3B, which has been cleared by K083821 in May 14, 2009.

PM-2000XL Pro could be configured with two different NIBP modules, one is EDAN NIBP module, the other one is Omron M3600 NIBP module; M3600 module used in PM-2000XL Pro is the same to that used in BX-10, which has been cleared by K032857 in April.21.2003.

The **C02** module and Nellcor SpO_2 module used in PM-2000XL are the same to those used in M3B, which has been cleared by K083821 in May 14, 2009.

Arrhythmia and ST Analysis used in PM-2000XL Pro is the same to that in PC EGG which has been cleared by FDA under K102854 and K092010.

Intended Use:

PM-2000XL Pro:
The monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (Sp02), Invasive or noninvasive blood pressure (2/4 channels IBP NIBP), Cardiac Output (CO), Temperature (dual-TEMP), Expired C02 and Anesthetic gas (AG). The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

PM-2000XL:
The monitor monitors parameters such as EGG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), Expired C02 and Quick Temperature (Quick TEMP. The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both. The arrhythmia detection and ST Segment analysis are not intended for neonatal patients.

Effectiveness and Safety Contraindications:

Comparison to the predicate device:

The subject device has similar technology characteristics and has the same intended use as the predicate device. The PM-2000XL & PM-2000XL Pro Patient Monitor has the same characteristics as the predicate device cleared under K110922. Both models use the same technology and manufacturing processes.

Substantially Equivalent Determination:

This premarket notification submission demonstrates that PM-2000XL & PM-2000XL Pro Patient Monitor is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 25 2012

Advanced Instruments, Inc.
c/o Jorge Millan, PhD.
Executive Director
Hialeah Technology Center, Inc.
601 West 20 Street
Hialeah, FL 33010

Re: K120631
Trade/Device Name: Patient Monitor, PM-2000XL & PM-2000XL Pro
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: Class II (two)
Product Code: MHX, CBQ, CBR, CBS, CCK, CCL, DQA, DRT, DSA, DSF, DSK, DXN, FLL, MLD
Dated: February 28, 2012
Received: March 2, 2012

Dear Dr. Millan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

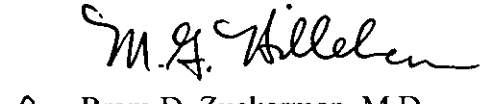
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120631

Device Name:

Patient Monitor models PM-2000XL & PM-2000XL Pro

Indications for Use:

PM-2000XL Pro:
The monitor monitors parameters such as ECG (3-lead, 5-lead, 12-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (Sp02), Invasive or noninvasive blood pressure (2/4 channels IBP NIBP), Cardiac Output (CO), Temperature (dual-TEMP), Expired C02 and Anesthetic gas (AG). The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

PM-2000XL:
The monitor monitors parameters such as EGG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), Expired C02 and Quick Temperature (Quick TEMP. The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both. The arrhythmia detection and ST Segment analysis are not intended for neonatal patients.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120631